OCT 2 7 2011

K110655

510(k) Summary

mahemedical

>> 510(k) Summary as required by section 807.92(c)

Submission Applicant:
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Date: 8/27/2011

Application Correspondent/Contact:
think!
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Germany
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Trade name: Mahe Perfect Spine - Pedicle Screw System

Common names: Pedicle Screw System, Spinal System, Spinal Fixation System, Stabilization System

Classification name: Spinal interlaminal fixation orthosis; Spinal intervertebral body fixation orthosis; Pedicle screw spinal system (21 CFR 888.3050, 888.3060, 888.3070)

Product codes: NKB, KWP, KWQ, MNH, MNI

Class: III

Predicate Devices:
> K051971 - OPTIMATM Spinal System, U&I Corporation
> K021564 - InCompass Spinal Fixation System, Spinal Concepts, Inc.
> K052123 - Pangea TM System, Synthes Spine

Description of the Device:
The Mahe Perfect Spine - Pedicle Screw System consists of a variety of shapes and sizes of rods, hooks, monoaxial and polyaxial screws, cross connectors, as well as appropriate instrumentation.

The Mahe Perfect Spine - Pedicle Screw System components are fabricated from titanium alloy per ASTM F136.

The system is sold non-sterile, the products have to be sterilized prior to use.

K110655

Indications for Use:
When used as a pedicle screw fixation system in the non-cervical posterior spine in skeletally mature patients, the Mahe Perfect Spine - Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), (5) tumor, and (6) failed previous fusion (i.e. pseudarthrosis). In addition, when used as a pedicle screw system placed between L3 and S1, the Mahe Perfect Spine - Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) in skeletally mature patients receiving fusion with autologous bone graft and with removal of the device after solid fusion is established.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the Mahe Perfect Spine - Pedicle Screw System is intended for use in skeletally mature patients and pediatric patients for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) tumor resection, and/or (7) unsuccessful previous attempts at spinal fusion (pseudoarthrosis).

When intended for anterolateral fixation of the T6-L5 spine the Mahe Perfect Spine - Pedicle Screw System is indicated for: (1) degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e. fracture or dislocation), (4) spinal stenosis, (5) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) tumor and (7) failed previous fusion.

Technological characteristics compared to the Predicate Devices:
The features of the subject components are substantially equivalent to the predicate devices based on similarities in classification, intended use, levels of attachment, materials, design, sizes and configurations. In addition, the manufacturing and sterilization methods of the predicate and subject components are similar.

Non-clinical performance data:
The following tests were performed on the worst case construct per ASTM F1717-10: static compression bending, static torsion and dynamic compression bending. Additional testing was also performed per ASTM F2193-02 and ASTM F1798. The mechanical testing demonstrates the comparable mechanical properties of the Mahe Perfect Spine – Pedicle Screw System to predicate devices.

Summary:
The presented data demonstrates that the Mahe Perfect Spine - Spinal Fixation System should perform similarly to the predicate devices. The Mahe Perfect Spine - Spinal Fixation System can be deemed substantially equivalent for its indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mahe Medical GmbH
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Ms. Andrea Pecsi
Schwarzwaldstraße 5
78532 Tuttlingen, Germany

Re: K110655
Trade/Device Name: Mahe Perfect Spine – Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: August 29, 2011
Received: September 26, 2011

Dear Ms. Pecsi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110655

Device Name: **Mahe Perfect Spine - Pedicle Screw System**

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110655